Go To Table Of Contents

Installation & Operation Manual

MIDMARK®

M11D UltraClave™ Steam Sterilizer

Important Information *Page 2*

Installation *Page 4*

Description *Page 6*

Components Overview *Page 8*

Controls & Indicators *Page 9*

Operation *Page 11*

Operator Maintenance *Page 20*

Calling For Service *Page 29*

Specifications *Page 29*

Limited Warranty *Page 30*

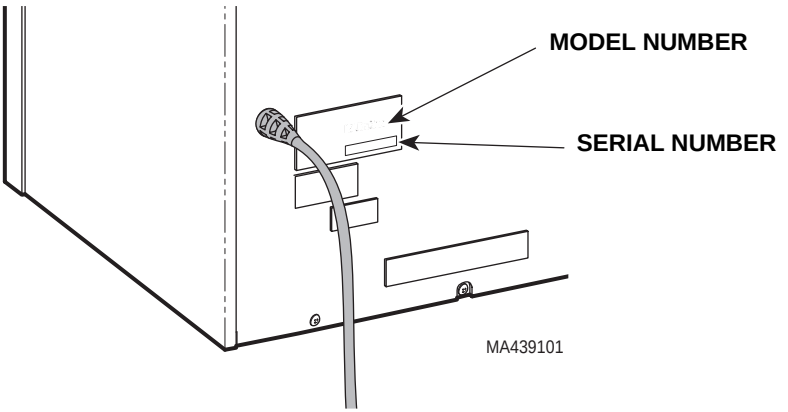
Go To Table Of Contents

Owner's Product Identification

(information that you will need to provide for servicing - key information is highlighted)

Date of Purchase	***Serial Number***
Name of Owner / Facility / Department	***Model Number***
Name of Authorized Dealer	Telephone # of Authorized Dealer
Address of Authorized Dealer	

MODEL AND SERIAL NUMBER LOCATION



CONTENTS

IMPORTANT INFORMATION 2
- Scope and Purpose of This Manual 2
- Intended Use of Product 2
- Safety Instructions 2
- Explanation of Safety Symbols and Notes 3
- Transportation and Storage Conditions 3

INSTALLATION 4
- Location Requirements For Sterilizer 4
- Re-Location Requirements For Sterilizer 5
- Electrical Requirements 6

DESCRIPTION 6
- Operational Features 6
- Mechanical Features 7
- Safety Features 7

COMPONENTS OVERVIEW 8

CONTROLS & INDICATORS 9

OPERATION 11
- Recommended Steam Sterilization Monitoring Program 12
- Sterilizer Preparation Before Operation 12
- Cleaning Instruments 13
- Guidelines For Loading Trays 14
- Operation 16
- Standard Cycle Parameters 19
- List of Authorized Accessories 20

OPERATOR MAINTENANCE 20
- Daily 20
- Weekly 20
- Monthly 21
- Quarterly 23
- Toubleshooting Guide 24
- Error Code Guide 26

CALLING FOR SERVICE 29

SPECIFICATIONS 29

LIMITED WARRANTY 30

PRINTER INSTALLATION AND OPERATION 31
- Installing the Printer 31
- Operating the Printer 34
- Inserting the Paper Roll 34
- About the Cartridge Ribbon 35
- Installing a New Cartridge Ribbon 36
- Removing the Paper Roll 37
- Power Up Message 37
- Printer Tape Description 37

IMPORTANT INFORMATION

Scope and Purpose of This Manual

This manual provides complete instructions for the installation, operation, and normal care of the M11D UltraClave™ Steam Sterilizer. It is intended that this manual be used by all personnel operating the sterilizer or performing operator level maintenance. No repair information is included in this manual as no repairs are authorized at the operator level.

Intended Use of Product

The M11D Ultraclave is intended to be used in medical and dental offices, hospitals, clinics, nursing homes, laboratories, and other facilities to sterilize heat stable and moisture stable, reusable equipment. Dental handpieces can be sterilized in the M11D in the Pouches cycle. This device is not recommended for sterilization of liquids intended for direct patient contact. Refer to Standard Cycle Parameters on page 19 in this manual for detailed information.

Safety Instructions

The primary concern of Midmark is that this equipment is operated and maintained with the safety of the patient and staff in mind. To assure safer and more reliable operation:

- Read and understand this manual before attempting to install or operate the sterilizer.
- Assure that appropriate personnel are informed on the contents of this manual; this is the responsibility of the purchaser.
- Assure that this manual is located near the sterilizer, or if possible, permanently affixed to the sterilizer.

Explanation of Safety Symbols and Notes

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury. The DANGER symbol is limited to the most extreme situations.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices.

EQUIPMENT ALERT

Indicates an imminently or potentially hazardous situation which, if not avoided, will or may result in serious, moderate, or minor equipment damage.

NOTE

Amplifies an operating procedure, practice, or condition.

Transportation and Storage Conditions

EQUIPMENT ALERT

The water must be drained from the unit's reservoir before transporting or storing at 0°C (32°F) or below. Also, the unit should be allowed to reach room temperature before operating. Failure to do so could result in damage to unit.

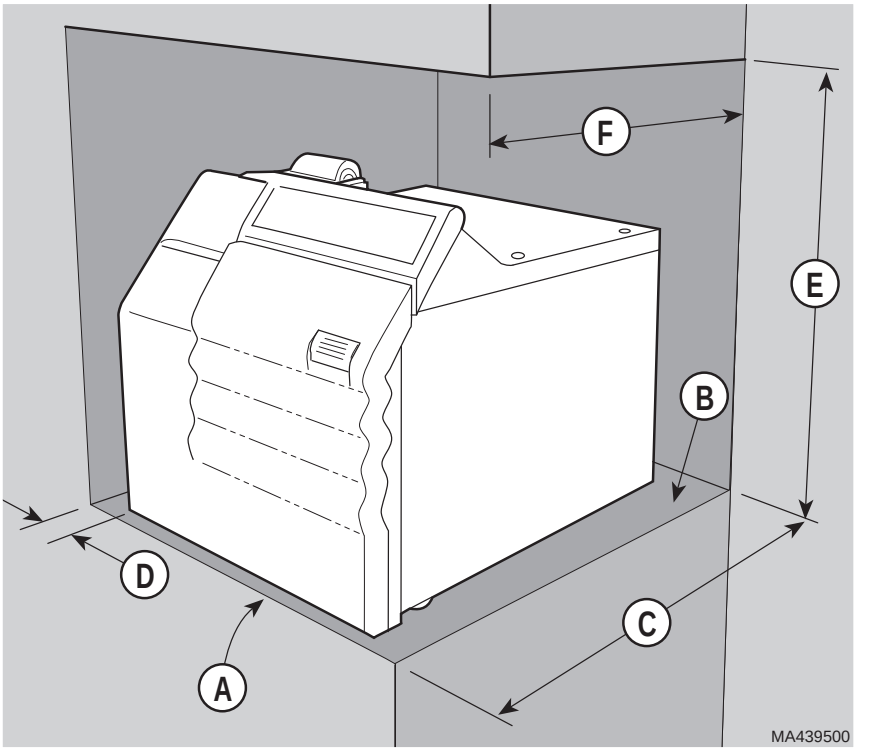
- Ambient Temperature Range: ..... -40°C to +70°C (-40°F to 158°F)
- Relative Humidity ..... 10% to 90% (non-condensing)
- Atmospheric Pressure ..... 500hPa to 1060hPa (0.49atm to 1.05atm)

INSTALLATION

Location Requirements For Sterilizer

DANGER
Do not operate this sterilizer in areas where flammable anesthetics are used or stored. An explosion could occur, causing personal injury.

Adherence to the following recommendations for location of the sterilizer will contribute to optimum performance of the unit:



Support Surface (A) - Sterilizer must be placed on a level surface to ensure that the chamber will fill correctly. Improper water level in the chamber could cause a sterilizer malfunction.

Support Surface Material (B) - Formica, stainless steel, or other water and heat resistant material. Heat from bottom of sterilizer could reach 71°C (160° F) on the support surfaces for short periods of time.

Support Surface Depth (C) - Support surface should be approximately 53.3 cm (21 in) deep. Allow at least 5.1 cm (2 in) clearance behind the sterilizer for air circulation.

Distance To Side Wall (D) - If the sterilizer is located next to side walls, there should be no less than 5.1 cm (2 in) clearance between the side of the sterilizer and the wall.

Distance Above Sterilizer (E) - If the sterilizer is to be located beneath wall cabinets or shelves, the underside of the cabinets or shelves should be at least 58.4 cm (23 in) above the support surface, to provide access to the top inspection cover and to allow for changing the printer paper roll.

Overhang (F) - If the sterilizer is to be located beneath an overhang, the underside of the overhang should project no further than 38.1 cm (15 in) over the rear of the sterilizer.

Location On Support Surface - The front of the sterilizer should be located near the front of the support surface so water can be easily drained from the tube into a container.

Neighboring Materials and Equipment - If the sterilizer will be operated in continuous cycles, locate the sterilizer where excessive emission of steam will not damage materials or equipment in the surrounding area.

Re-Location Requirements For Sterilizer

1. Disconnect power cord from the electrical outlet and allow sterilizer to cool.
2. Drain water from reservoir or take care not to tip the sterilizer, which will allow water to spill from reservoir.

Electrical Requirements

WARNING

Use 220 - 240 VAC, 50/60 HZ alternating current only for 230 VAC models and 90 - 110 VAC, 50/60 HZ alternating current only for 100 VAC models. Failure to do so could result in electrical shock to personnel and will result in damage to sterilizer.

Do not use this sterilizer in an explosive or oxygen-enriched atmosphere. Failure to do so could result in serious personal injury or death.

NOTE

Grounding reliability can only be achieved if this unit is connected to a matching three-pronged, grounded, isolated, correctly polarized receptacle.

The electrical rating for the 230 VAC unit is 230 VAC, 50/60 Hz, 10 amps. The electrical rating for the 120 VAC unit is 120 VAC, 60 Hz, 15 amps. The electrical rating for the 100 VAC unit is 100 VAC, 50/60 Hz, 20 amps. The three-pronged grounding plug on the sterilizer power cord must be plugged into a matching three-pronged, grounded, isolated, correctly polarized receptacle. Check the serial number label on the back panel of the sterilizer to verify the voltage rating for the unit.

DESCRIPTION

Operational Features

The M11D UltraClave™ sterilizers . . .

- will begin a sterilization program cycle when a sterilization program is selected, the door is closed and fully latched, and the START switch is pressed.
- will automatically fill the chamber with water to the correct level once the START switch is pressed.
- begin the cycle time countdown only after the proper pressure and temperature have been reached.
- automatically exhaust the steam pressure from the chamber upon completion of the sterilization phase. Five beeps signal the operator to open the door to initiate the drying phase (this signal is repeated every five minutes until the door is opened or 30 minutes have elapsed).
- automatically starts a 30 minute drying phase. Items that do not require drying may be removed any time after the sterilization phase is complete. **Sterility of unwrapped items and moist wrappings is compromised on**

exposure to a non-sterile environment.

- will signal the operator that the drying phase and therefore the sterilization program cycle is complete by sounding seven audible “beeps”. The sterilizer may be switched to standby at this time or restarted if additional sterilization programs are desired.

Mechanical Features

The M11D UltraClave™ sterilizers . . .

- have a tray rack which can hold two small and two large trays. The tray rack can be removed for periodic cleaning of the chamber, tray plate, tray rack, and filter.
- have an optional printer which provides a permanent record of actual exposure times and temperatures.
- have a removable power supply cord (100 and 230 VAC units only).
- have a two gaskets in the door; a dam gasket and a door gasket which can easily be replaced by operator in seconds.

Safety Features

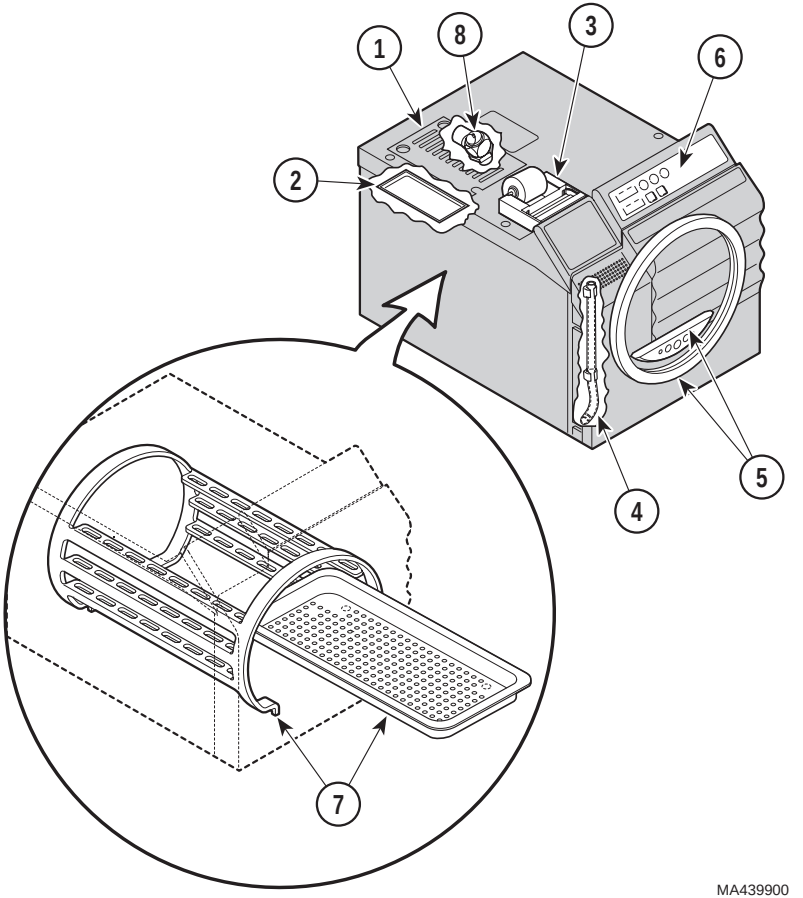
The M11D UltraClave™ sterilizers . . .

- have a ***door stop*** which prevents the door from opening fully if there is a slight residual pressure in the chamber when the door handle is operated. The door stop also retains the door in a partially open position during the drying cycle.
- have a ***door closed switch*** which is used to signal the sterilizer that the door is completely closed. This switch is activated just as the door becomes fully closed. An audible signal will sound and “C002” will flash in the display window if the door is not fully closed during the fill mode.
- have a ***water low indicator*** which signals the operator if there is insufficient water to fill the chamber to the proper level. An audible signal will sound and “C001” will flash in the display window if the reservoir needs to be refilled with water.
- have their ***chamber temperature monitored*** during a cycle to prevent an overheat condition. If chamber temperature reaches or exceeds 146°C (295°F), power to the sterilizer is cut off.
- have a ***pressure relief valve*** which opens to provide backup protection to reduce chamber pressure in the event that the chamber steam pressure exceeds the allowable limit. Released steam is directed out of the bottom of the unit’s cabinet. An access cover is located on the top cover for relief valve operational checks.

- have a ***fault detection circuit*** which monitors all functions of the sterilizer during a cycle. If a fault occurs during a cycle, the sterilizer monitoring circuitry will stop the cycle, sound an audible signal, and display an error code in the display window.

COMPONENTS OVERVIEW

The illustration below shows the location of the sterilizer's major components and the chart below provides their descriptive name.



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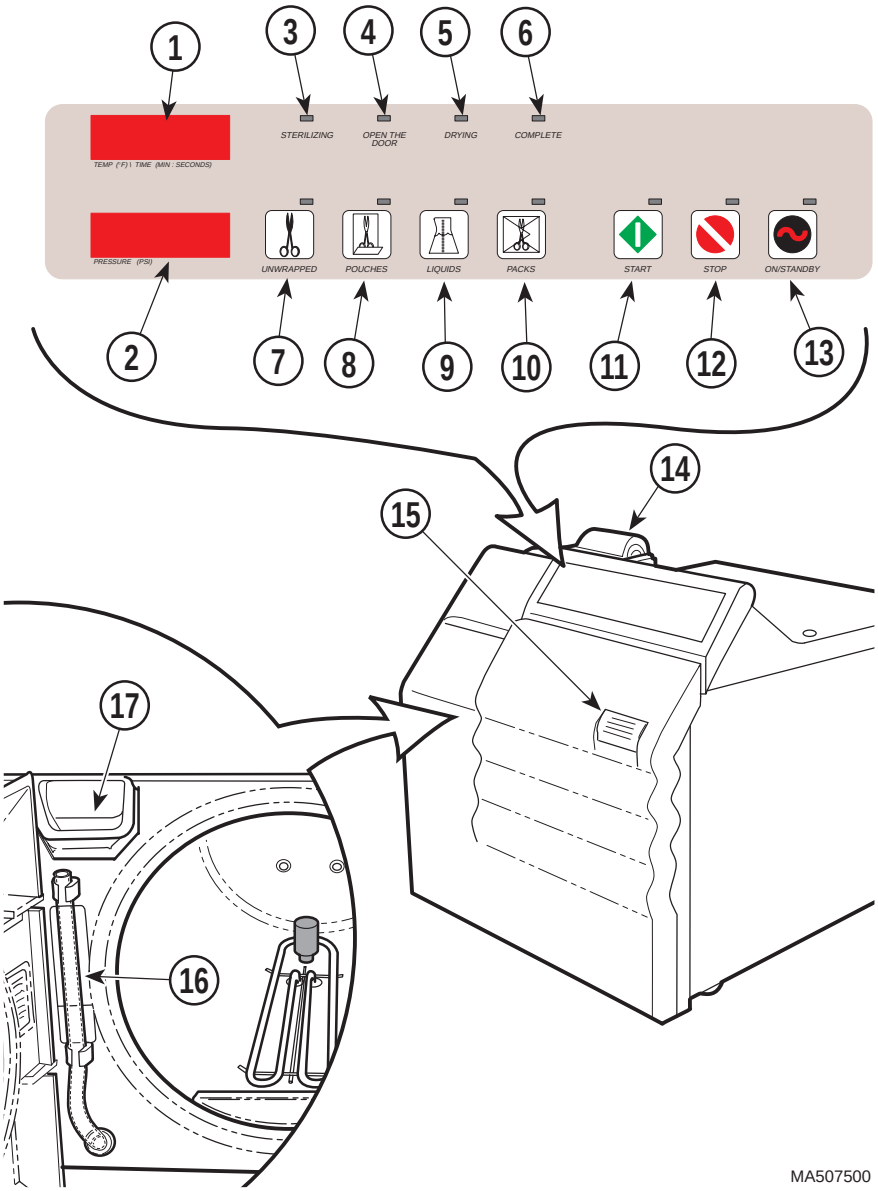
DESCRIPTION OF COMPONENTS

1. Access Cover	5. Door and Dam Gaskets
2. Reservoir Lid	6. Display / Control Pad
3. Printer (Optional)	7. Wire Tray Rack and Tray Plate
4. Level Indicator / Reservoir Drain Tube	8. Pressure Relief Valve

CONTROLS & INDICATORS

The following illustrations show the location of the sterilizer's controls and indicators and the chart on the following pages describes their function.



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Ref.	Control	Function
1	*Temperature / Time display - Error Code Display*	*alternately indicates cycle temperature and exposure time when a cycle is selected. During a cycle, the cycle time remaining is displayed.* *Also, indicator flashes (and a beep sounds) when a cycle is terminated before completion.* ***NOTE:*** *a corresponding error code is displayed on the Temperature / Time display any time an error occurs. See Error Code Guide for a detailed explanation of each error code.*
2	*Pressure display*	*indicates current chamber pressure during a cycle.*
3	*STERILIZING indicator*	*illuminates during the heat up and sterilization phases of a cycle.*
4	*OPEN THE DOOR indicator*	*illuminates after the sterilization phase is complete. It tells you to "open the door" in order to initiate the drying phase.*
5	*DRYING indicator*	*illuminates during the drying phase of a cycle.*
6	*COMPLETE indicator*	*illuminates when a cycle is complete, indicating that the sterilized goods may be removed at this point.*
7	*UNWRAPPED button*	*when pressed, selects a program cycle designed to process unwrapped instruments at 132°C (270°F) for 3 minutes with a 30 minute drying cycle following the sterilization phase.*
8	*POUCHES button*	*when pressed, selects a program cycle designed to process instruments and dental handpieces in combination paper / plastic sterilization pouches or wrapped instruments at 132°C (270°F) for 15 minutes with a 30 minute drying cycle following the sterilization phase.*
9	*LIQUIDS button*	*when pressed, selects a program cycle designed to process non-volatile liquids at 121°C (250°F) for 30 minutes.*
10	*PACKS button*	*when pressed, selects a program cycle designed to process packs of instruments at 121°C (250°F) for 30 minutes with a 30 minute drying cycle following the sterilization phase.*
11	*START button*	*when pressed, initiates the program cycle that has been selected.*
12	*STOP button*	*when pressed, terminates the program cycle currently in progress.*

Ref.	Control	Function
13	*ON / STANDBY button*	*when pressed, turns the sterilizer ON or into STANDBY mode. If the ON / STANDBY button is pressed during a cycle, the program cycle is aborted. In Standby mode, all program buttons and indicator lights are locked out to prevent accidental program initiation.*
14	*Printer*	*the printer (optional equipment) can be used on all models to provide a permanent record of the time, temperature, and pressure reached during a cycle. Refer to the Printer section later in this manual for detailed information on printer features and operation.*
15	*Door Handle*	*used to open or latch the door. The door handle is raised to unlatch the door and lowered to latch the door.*
16	*Level Indicator / Reservoir Drain Tube*	*indicates the water level in the reservoir. Also, the tube may be detached from its clips and used to drain the reservoir quickly and easily into a suitable container.*
17	*Fill opening*	*allows distilled or demineralized water to be poured into the reservoir from the front of the unit (with door in open position).*
Message Code C001	*Water Low message [viewed on display (1)]*	*indicates that there is not enough water in reservoir tank to fill chamber. Add distilled or demineralized water to reservoir tank.*
Message Code C002	*Door Ajar message [viewed on display (1)]*	*indicates that the chamber door not fully closed. Shut chamber door properly.*
Message Code C003	*Door Not Opened message [viewed on display (1)]*	*Indicates that drying portion of cycle cannot be initiated because the door was not opened within 30 minutes after venting portion of cycle was complete. Rerun cycle.*

OPERATION

DANGER

Do not use this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.

If the sterilizer malfunctions, immediately unplug sterilizer. If the sterilizer continues to malfunction, call for service; do not attempt to repair the sterilizer yourself.

EQUIPMENT ALERT
For optimal sterilizer performance, allow the sterilizer to reach room temperature before operating.

Recommended Steam Sterilization Monitoring Program

Physical monitors (temperature and pressure measuring devices) can be used to help detect failures in sterilizer function. The sterilizer notifies the user if sterilization conditions fall outside of established limits. It is recommended that the Printer Accessory be used to create a record of each load's actual cycle time, temperature, and pressure.

Process monitors, such as biological indicators and chemical indicators, should be included in each sterilization cycle. The process monitors detect whether the cycle parameters were delivered. Process monitors cannot establish that a processed item is actually sterile. If the monitors detect a failure, the user must determine the source of the failure. Failures could result from improper packaging, loading, or sterilizer malfunction. Follow the process monitor manufacturer's instructions for proper selection, storage, use, and interpretation of their devices.

Follow the appropriate agency (state dental or medical board) for sterilization monitoring guidelines for your office. Additional information can also be obtained from CDC, AAMI, OSAP, and ADA regarding monitoring programs or other sterilization issues.

Sterilizer Preparation Before Operation

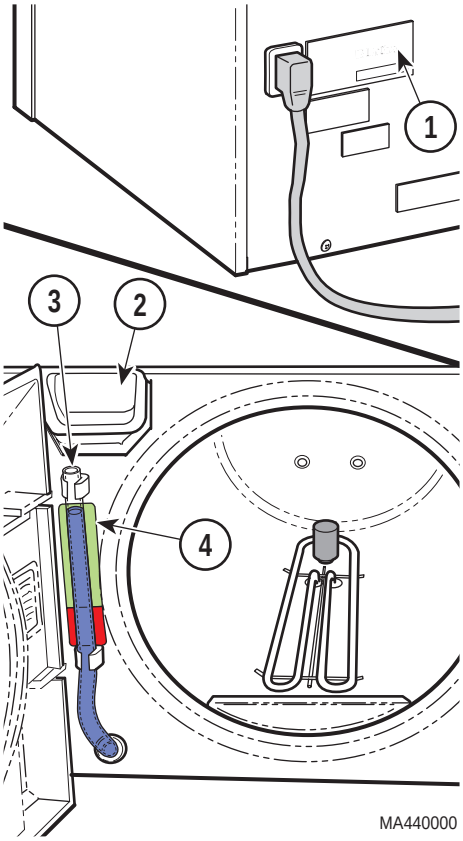
EQUIPMENT ALERT
Check the serial number label (1) on the back panel of the sterilizer to verify the voltage rating for the unit. Failure to do so could result in damage to the unit.

1. Locate the sterilizer and plug in its power cord in accordance with the Installation instructions contained earlier in this manual.

EQUIPMENT ALERT
Use only distilled or demineralized water. Normal tap water contains minerals, especially chlorides, which have corrosive effects on stainless steel. Failure to use distilled or demineralized water may cause serious deterioration and premature failure of the stainless steel chamber which could result in serious injury or death.

2. Open the door and pour distilled or demineralized water into the fill opening (2) until the water level found in the Level Indicator Tube (3) is at the top of the red / green fill level label (4).

3. If the unit has a printer (optional equipment), turn the printer to ON.



Cleaning Instruments

DANGER

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in unsterile instruments which could lead to personal injury or death.

1. Clean instruments in accordance with instrument manufacturers' and OSHA's recommendations.

2. Thoroughly wash instruments to remove gross debris (either mechanically or using an ultrasonic cleaner).

3. Rinse instruments thoroughly.

4. Dry instruments.

Guidelines For Loading Trays

Sterilizer loading is critical to effective sterilization. Protective coverings designed to be used in steam sterilization processes should be used to help ensure that items retain sterility until used. A proper load for a sterilizer is determined by the number of items to be sterilized, their characteristics, and how they are prepared and positioned within the sterilizer. A single large item may be the maximum load for that type of item while the maximum load for very small items may contain hundreds of items. Large and small items can be included in the same load. The sterilization process will be effective if items are properly prepared and positioned, so they get adequate contact with steam for the correct amount of time.

The M11D sterilizers are equipped with two large and two small trays to maximize the number of items that can be processed at one time and provide separation for better steam flow and penetration. Four properly loaded trays, as noted in the chart on page 15 (two large and two small), is the maximum load for the M11D sterilizers.

General Guidelines

- Sterilize jointed instruments in an open position.
- Place all containers so the opening allows steam to enter and air to leave the container (containers are usually positioned on their side or with the opening tilted slightly down).
- Pouch or wrap items to preserve sterility after processing. Use only protective coverings designed and recommended for use with steam sterilization.
- Do not wrap items too tightly. Steam penetration will be affected if an item has excessive wrapping.
- Do not stack trays on one another. Using Midmark's standard tray rack and trays provides proper tray spacing.
- Position loads on trays with appropriate space between items. Adequate space is required between items to allow proper steam flow and drying.
- Place unwrapped items on a towel or absorbent paper.
- Vented liquid containers should not be filled to more than 75% of their capacity to allow for fluid expansion and to prevent overflow. Depending on the user's desired results, many different container styles may be acceptable. Careful consideration of the liquid to be sterilized should guide the user in selection and use of appropriate containers and closures. Always consult the liquid and/or container manufacturer for information on sterilization. ***Not recommended for sterilization of liquids intended for direct patient contact.***

Loads Including Dental Handpieces and/or Instruments

NOTE
Dental handpieces should only be sterilized when placed in the pouch rack and in the POUCHES cycle. Only one handpiece should be placed in each pouch.

The maximum M11D load shall be nine handpieces (in the pouch rack) and 75 instruments. Other combinations of fewer handpieces and items can be processed in a single load if that allows for efficient sterilization. If a load surpasses these limits, we recommend dividing the load and running multiple cycles. Listed below are the maximum recommended loads for each tray:

	Maximum Capacities		
Load Type	**M11D Large / Deep Tray**	**M11D Small Tray**	**Sterilizer Total**
Solid Items	45 instruments - 1200 grams (2.7 lbs.) ***or***	30 instruments - 800 grams (1.8 lbs.) ***or***	150 instruments - 4.1 kg (9.0 lbs) ***or***
Handpieces	9 in rack ***or***	9 in rack ***or***	9 handpieces in rack and 75 instruments ***or***
Liquids **(†)**	3 - 200 ml (6.76 oz) containers **or**	2 - 200 ml (6.76 oz) containers **or**	3 - 200 ml (6.76 oz) containers **or**
Packs **(‡)**	4,424.5 cu. cm up to 5.0 cm thick (270 cu. in. up to 2 in. thick)	3,195.5 cu. cm up to 5.0 cm thick (195 cu. in. up to 2 in. thick)	15,240 cu. cm up to 5.0 cm thick (930 cu. in. up to 2 in. thick)

† *Not recommended for sterilization of liquids intended for direct patient contact.*

‡ *Packs to have a minimum of 1/4 in. (6.3 mm) space between each other and away from all sterilizer surfaces.*

Operation

WARNING

Do not use this sterilizer in an explosive or oxygen-rich atmosphere, or where flammable anesthetics are stored. To do so could result in an explosion or fire.

Do not use this sterilizer for sterilizing volatile substances or for any purpose other than its intended design. Burns and toxic or explosive conditions could result.

Clean and dry instruments before putting them into the sterilizer. Incomplete and improper cleaning of instruments will impede sterilization and will result in unsterile instruments which could lead to personal injury or death.

If the sterilizer malfunctions, immediately unplug sterilizer. If the sterilizer continues to malfunction, call for service; do not attempt to repair the sterilizer yourself.

Do not force door handle at any time. Chamber pressure may cause door to open with extreme force. If the door handle does not move freely, allow unit to cool and depressurize for 40 minutes before opening door. Failure to adhere could result in serious personal injury or death.

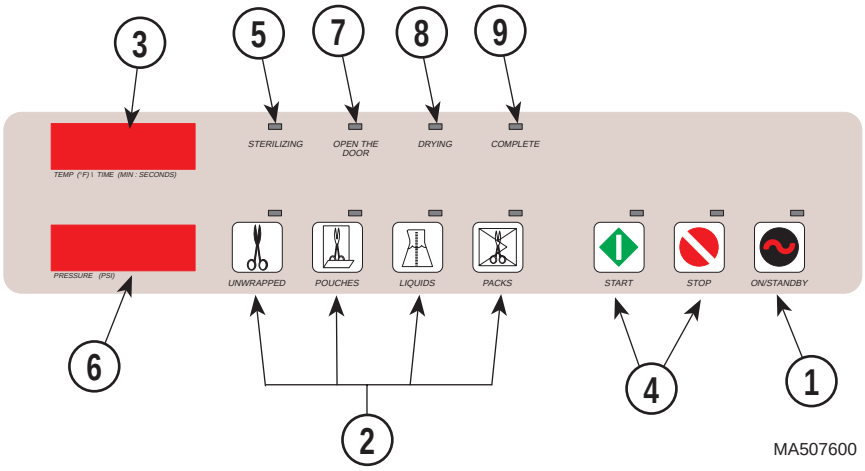
EQUIPMENT ALERT

Do not use toweling or packaging which may contain chlorine bleach residue. Doing so could result in trays and/or chamber rusting or discoloring. In extreme cases, the life of the chamber may be significantly shortened.

NOTE

Use sterility monitors with each sterilization load. Also, if a sterilizing cycle is terminated prematurely, reprocess the instruments to ensure the sterility of the load.

Refer to the following steps for a detailed description of the program operating procedures:



1. Press the ON / STANDBY button (1).
   - The Selector / Indicator panel turns on (displays will illuminate).
   - The Program Indicator lamps (2) flash until a sterilization program is selected.

NOTE
Before operating the sterilizer, be sure the door handle is completely depressed (latched). If the handle is not fully latched, the sterilizer will alert the operator with an audible beep and will not start until the door handle is latched.

2. Close and latch the door; the sterilizer will not operate unless the door is closed.

EQUIPMENT ALERT
Processing goods using an incorrect sterilization program could result in unsterile goods and may damage instruments. Consult with your supply manufacturer for specific sterilization instructions.

3. Select a sterilization program in accordance with the Standard Cycle Parameters (see table later in this manual).
   - The Temperature / Time display (3) displays the selected program's parameters alternately.
   - If an incorrect program selection is made, select the correct program cycle by pressing the correct program cycle button (2).

4. Press the START button (4).
   - The sterilizer automatically begins processing its sterilization load.

- The chamber fills automatically with water to the correct level.
- The STERILIZING lamp (5) illuminates, indicating that the sterilizer is in the heating and sterilization phase of the selected cycle.
- When correct temperature (3) and pressure (6) are reached, the sterilizer begins its time countdown. The selected exposure time and temperature are maintained throughout the sterilization phase.
- When exposure time is complete, the sterilizer vents the chamber of all steam and water back into the reservoir tank.

WARNING

To avoid possible burns, use caution when opening the door. Open door to first catch and let steam dissipate.

- When venting is complete and the pressure inside the chamber is reduced to zero, the sterilizer signals the operator that it is time to open the door by flashing the OPEN THE DOOR lamp (7), flashing “dddd” in the display window (3), and emitting five audible beeps. The audible signal repeats every five minutes until the door is opened or 30 minutes have elapsed. If 30 minutes elapses and the door has not been opened, the drying phase can no longer be initiated.

5. Open the sterilizer door to its first stop.
   - Once the door is opened, the DRYING lamp (8) illuminates and the sterilizer begins a 30 minute drying phase (unless Liquids cycle was selected).
   - Leave the sterilization load in the chamber to dry or remove the sterilization load from the chamber if drying is not necessary.

NOTE

The sterility of wrapped or packed instruments cannot be ensured unless the wrapped or packed instruments are allowed to dry fully.

- When the 30 minute drying phase is complete, the sterilizer signals the operator that the drying phase is complete with seven audible beeps and the COMPLETE lamp (9) illuminates to indicate that the program cycle is complete.

CAUTION

The processed load and metal inner surfaces will be hot at the completion of the drying phase. Avoid contact. Failure to do so could result in serious burns.

6. Remove the sterilizer load from the chamber.

7. Press the ON / STANDBY button (1) to return the sterilizer to the STANDBY mode ***or*** if additional sterilization program cycles are desired, restart the sterilizer at this time.

Standard Cycle Parameters

The following table lists the standard cycle parameters for the four different types of sterilizer loads (follow state and federal guidelines regarding sterilization of single use devices and instruments).

Standard Cycle Parameters

CYCLE	TEMP / PRESSURE/TIME (minimums)	ITEMS TO BE STERILIZED ***(Always consult the item manufacturer's recommendations for sterilization.)***
Unwrapped	132°C (270°F) / 186 kPa (27 psi) for 3 minutes	Instruments loose on a tray. Open glass or metal canisters. Tubing not used in surgical procedures. Items manufacturers recommend for exposure at 132°C (270°F) for 3 minutes. The sterility of unwrapped items is compromised on exposure to a non-sterile environment.
Pouches	132°C (270°F) / 186 kPa (27 psi) for 15 minutes	Instruments and dental handpieces. Loosely wrapped individual instruments. Multiple layers of instruments separated by fabric. Wrapped trays of loose instruments. Tubing not used in surgical procedures. Items manufacturers recommend for exposure at 132°C (270°F) for 15 minutes.
Liquids	121°C (250°F) / 104 kPa (15 psi) for 30 minutes	Liquids or gels that could boil over with rapid depressurization. Cycle includes special vent and dry functions. ***Not recommended for sterilization of liquids intended for direct patient contact.***
Packs	121°C (250°F) / 104 kPa (15 psi) for 30 minutes	Textiles and surgical packs wrapped for sterilization. Items, except liquids, manufacturers recommend for exposure at 121°C (250°F) for 30 minutes.

List of Authorized Accessories

Listed below are the accessories which are authorized for use with this sterilizer:

Accessory Name	Order Number
• Printer Accessory	9A155001
• Speedclean, 1 bottle	002-0269-00
• Speedclean, 1 case (12 bottles)	002-0269-01
• M11D Horizontal Cassette Rack	9A215001
• M11D Vertical Cassette Rack	9A215002
• M11D Sterilizer Deep Tray	9A225001
• Sterilizer Pouch Rack	9A226001

OPERATOR MAINTENANCE

It is the responsibility of the user to establish a periodic maintenance procedure to assure correct operation of the equipment and reliable sterilization of the loads. Contact your local distributor or representative to develop a program for planned maintenance.

Daily

1. Clean External Surfaces - Wipe with a soft dry cloth and wash occasionally with a damp cloth and mild soap or detergent.

WARNING

Make sure that the unit is cool when cleaning the door gasket and any mating surfaces. Failure to do so could result in serious burns to hands.

2. Clean Sterilizer Door Gasket - Clean door gasket and mating surface with a damp cloth. Examine gasket for possible damage that could prevent a good sealing surface.

Weekly

EQUIPMENT ALERT

Do not use abrasive or bleaching agents in the chamber (i.e. steel wool, scouring powder, bleach, etc.). Also, never use a wire brush. If these materials are used, possible damage to the metal surfaces of the chamber and other components could result.

1. Clean Chamber and Trays - The sterilizing chamber and instrument trays should be cleaned weekly. First, drain the water from the reservoir. A drain

tube is located on the front of the unit for draining. Wash the inside of the chamber and the trays with mild soap or Speed-Clean and distilled or demineralized water. Refill the reservoir with distilled or demineralized water.

Monthly

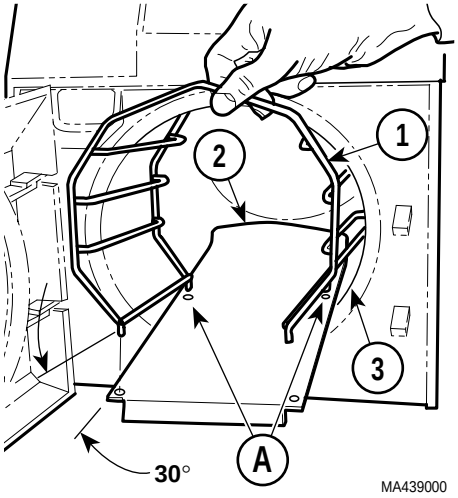
1. Flush the System - To protect the intricate parts of the unit, the system must be flushed once a month with Speed Clean Sterilizer Cleaner:

   (a) Drain reservoir and fill with clean, distilled water then add one ounce of Speed Clean Sterilizer Cleaner to a cool chamber.

   (b) Run one 30 minute cycle (PACKS) at 121°C (250°F). Instruments must not be sterilized while cleaning the sterilizer.

   (c) Drain reservoir fill with clean distilled or demineralized water and run one 3 minute cycle (UNWRAPPED) at 132°C (270°F).

   (d) Drain reservoir and allow sterilizer to cool to room temperature. Remove the trays, tray rack (1), and the tray plate (2). This is accomplished by grasping the tray rack (1) on both sides in the front and gently pulling outward. The tray rack and tray plate should slide out of the chamber together.



   (e) Wipe out the inside of the chamber being careful not to damage the heater element or the temperature and level sensor components. Wipe off the trays, tray rack, and tray plate.

   (f) Re-install the tray rack (1) and tray plate (2) in the chamber as follows: Position the two rear posts of tray rack in rack holes (A) of tray plate. Then, hold front end of tray rack at approximately a 30° angle from the tray plate. Then, insert rear end of tray rack and tray plate as an assembly in chamber (3). Push tray rack and tray plate into chamber completely. Re-install the trays.

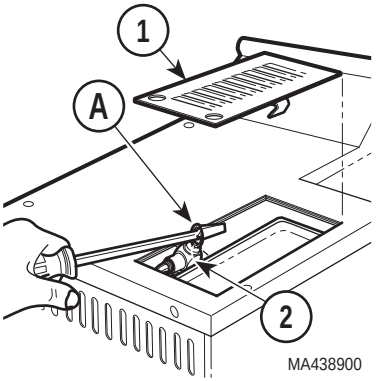
   (g) Refill the reservoir with clean distilled or demineralized water.

(h) Refill the reservoir with clean distilled or demineralized water.

2. Perform Pressure Relief Valve Check - The pressure relief valve must be checked each month by a qualified person to be sure that the relief valve is functioning properly:

(a) Remove the top inspection cover (1).

(b) Select the UNWRAPPED cycle and START the cycle.



WARNING

The pressure relief valve will be hot. Do not use bare hands to pull wire ring; use a screwdriver or rod. Failure to do so will result in burns to hands. Also, steam will be vented from under the rear of the sterilizer. To keep from being burned, place a steam barrier (a rolled up towel around the bottom of the sterilizer.

(c) When the "heat up" portion of the cycle is complete and the elapsed time is being counted down on the display panel, pull upward on wire ring (A) of pressure relief valve (2) with a screwdriver for approximately 3 seconds; steam should discharge freely from beneath the rear of the unit.

NOTE

If the pressure relief valve does not close completely when the wire ring is released, pull the wire ring again and release it quickly so the valve snaps back into position. Do this until the valve seats properly.

(d) Release the wire ring of pressure relief valve (2). The steam should vent out of the pressure relief valve until the wire ring is released. When the wire ring is released, the valve should seat, stopping the release of steam.

(e) Press STOP to prevent the unit from overheating.

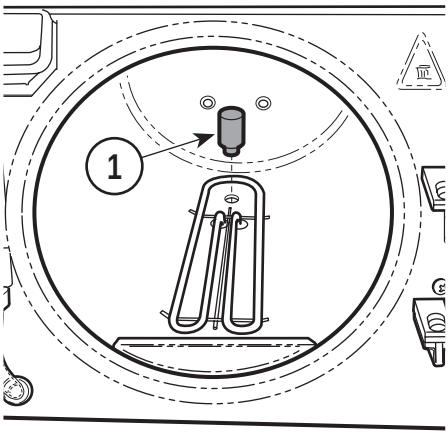
(f) If excessive force is required to open pressure relief valve (2) or pressure relief valve will not reseat properly, the pressure relief valve must be replaced (See Calling For Service later in this manual).

(g) Install top inspection cover (1).

3. Cleaning Chamber Filter:

   (a) Before performing this procedure, make sure that the sterilizer has cooled to room temperature.

   (b) Open the sterilizer door and remove all trays, tray rack, and tray plate from the chamber. Locate the chamber filter (1) on the bottom of the chamber.



MA438800

NOTE
If the filter cannot be cleaned effectively, the filter must be replaced.

   (c) Grasp the filter (1) and gently pull upwards while twisting slightly (a pair of pliers may be used if filter is stuck). The filter may be cleaned with mild soap and distilled or demineralized water. A small stiff bristled brush or ultrasonic cleaner may be helpful to remove foreign objects from the filter surface. Rinse the filter with distilled or demineralized water.

EQUIPMENT ALERT
Do not operate the sterilizer without the filter in place. Doing so could result in the sterilizer malfunctioning.

   (d) Replace the filter (1) by inserting the filter into the hole in the chamber bottom and pressing downwards while twisting slightly.

Quarterly

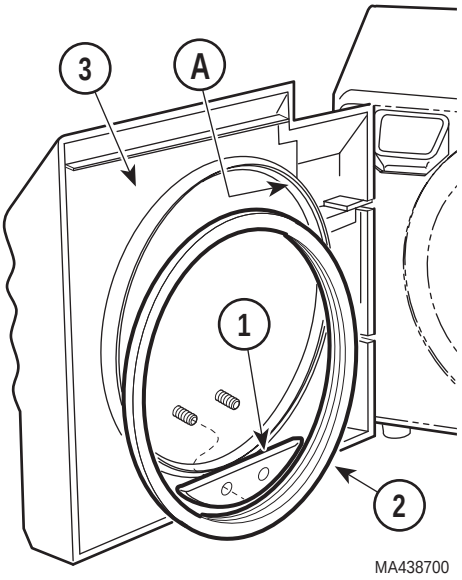
1. Remove and Clean Door Gasket - the door gasket and dam gasket must be removed and checked and the gasket housing channel must be cleaned as follows:

(a) Open sterilizer door. Then, remove dam gasket (1) and door gasket (2) from door (3).

(b) Clean the gaskets (1 and 2) with a mild detergent and inspect the gaskets for cracks, cuts, shrinkage, or swelling. Replace gaskets if necessary.

(c) Clean the gasket housing channel (A) with a solution of mild soap and distilled or demineralized water. A small brush (not wire brush) may be used to aid the cleaning.

(d) Press the door gasket (2) into the channel (A). Then, install dam gasket (1).



MA438700

(e) Run one cycle to seat the gaskets properly.

Troubleshooting Guide

Use the following table to assist in correcting minor problems with the sterilizer.

Troubleshooting Guide

Problem	*Possible Cause*	*Solution*
STERILIZING lamp does not illuminate within 5 minutes of starting a cycle and error code C001 is displayed.	*not enough water in reservoir tank to fill chamber.*	*add distilled or demineralized water to reservoir tank.*
STERILIZING lamp does not illuminate within 5 minutes of starting a cycle and error code C002 is displayed.	*Chamber door is not fully closed and / or latched.*	*Close the door properly and make sure the door is fully latched.*
An ERROR code is displayed on the display.	–	*See Error Code Guide for a detailed explanation*

Troubleshooting Guide - (Continued)

Problem	*Possible Cause*	*Solution*
Steam is escaping from the pressure relief valve.	*pressure relief valve was not properly reseated after pressure relief valve inspection*	*Reseat the pressure relief valve (see Perform Pressure Relief Valve Check under Monthly maintenance in this manual).*
Sterilization failure evidence from process monitor (chemical indicator, biological indicator, etc.)	*sterilization conditions were not present at the location of the indicator.*	*reload the sterilizer in accordance with Guidelines for Loading Trays. If the problem recurs, take the unit out of service and contact an authorized service representative (see Calling For Service later in this manual).*
	insufficient air removal, low temperature, or low pressure.	*take the unit out of service and contact an authorized service representative (see Calling For Service later in this manual).*
	indicator is out of date, is inappropriate for sterilizer cycle, or has malfunctioned.	*use an indicator, appropriate for the load and cycle selected, from a fresh supply that has been stored properly. Contact the indicator manufacturer for additional information on proper selection, use, storage, and potential misapplication or malfunction.*
Door gasket leaks.	*door gasket is damaged or dirty.*	*allow sterilizer to cool; then clean or replace door gasket (see Remove and Clean Door Gasket under Quarterly maintenance in this manual).*
	sterilizer is not level.	*level the sterilizer.*

Troubleshooting Guide - (Continued)

Problem	*Possible Cause*	*Solution*
Packs not dry	*sterilizer is overloaded.*	*reload the sterilizer in accordance with the Guidelines for Loading Trays. If the problem recurs, take the unit out of service and contact an authorized service representative (see Calling For Service later in this manual).*
	chamber filter is clogged.	*allow sterilizer to cool; then clean or replace filter (see Cleaning Chamber Filter under Monthly maintenance in this manual).*
	sterilizer is not level	*level the sterilizer.*
	input voltage is too low.	*have a qualified electrician connect sterilizer to a separate (dedicated) circuit with proper voltage level.*

Error Code Guide

Use the following table to determine the meaning of an error code and assist in correcting minor problems with the sterilizer.

Error Code Guide

Problem	*Possible Cause*	*Solution*
Operator Message Code C001	*Not enough water in reservoir tank to fill chamber.*	*Add distilled or demineralized water to reservoir tank.*
Operator Message Code C002	*Chamber door not fully closed.*	*Shut chamber door properly.*
Operator Message Code C003	*Drying portion of cycle was not initiated because the door was not opened within 30 minutes after venting portion of cycle was complete.*	*Rerun cycle.*
Error Code 1 *(power interruption to sterilizer)*	*unit powered up for first time.*	*press ON / STANDBY button and then continue normal operation.*

Error Code Guide - (Continued)

Problem	*Possible Cause*	*Solution*
	power was interrupted by power outage.	*press ON / STANDBY button and then continue normal operation.*
	overheat switch was activated.	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*
Error Code 2 *(STOP button pushed during cycle)*	_	*restart sterilizer after unit stops beeping.*
Error Code 3 *(ON / STANDBY button pushed during cycle)*	_	*restart sterilizer after unit stops beeping.*
Error Code 4 *(door ajar during cycle)*	*Door was opened during cycle.*	*restart sterilizer after unit stops beeping.*
	door switch not functioning properly.	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*
Error Code 5 *(excessive pressure)*	*sterilizer overloaded with gauze or linen packs.*	*reload the sterilizer in accordance with Guidelines for Loading Trays. If the problem recurs, take the unit out of service and contact an authorized service representative (see Calling For Service later in this manual).*
	Unit is out of calibration or bellows is not functioning properly.	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*

Error Code Guide - (Continued)

Problem	*Possible Cause*	*Solution*
Error Code 6 *(excessive temperature)*	*unit is out of calibration.*	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*
Error Code 7 *(pressure low during cycle)*	*leaking door gasket.*	*allow sterilizer to cool; then clean or replace door gasket (see Remove and Clean Door Gasket under Quarterly maintenance in this manual).*
	internal leak in unit plumbing.	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*
Error Code 9 *(pressure buildup in pressure vessel during drying cycle)*	*Pressure exceeds 14 kPa (2 PSI) during the dry mode.*	*Rerun cycle to ensure dryness of load. Sterilization cannot be ensured unless door is opened, allowing the load to dry completely before handling. Do not attempt to operate sterilizer again if error reoccurs. Contact an authorized service representative (see Calling For Service later in this manual).*
Error Code 10, 11, 12 *(hardware / software error)*	*Hardware is malfunctioning or software is corrupt.*	*allow sterilizer to cool completely. Restart sterilizer. If unit has errors again, unplug unit and contact an authorized service representative (see Calling For Service later in this manual).*

Calling For Service

If you are having a problem or have a question, refer to the inside front cover of this manual and call your dealer. Make sure that you have the information that is highlighted on the inside front cover of this manual available. If you can't resolve your question or problem with your dealer, call the following number:

Outside CE Union 1-800-Midmark (1-800-643-6275)
8:00 a.m until 5:00 p.m. (Eastern Standard Time in the U.S.)
Monday thru Friday, except for standard U.S. holidays.

Inside CE Union 33-2-430-517-76
Promotal
22, Rue De St. Denis
53500 Ernee, France

SPECIFICATIONS

Physical Dimensions:

Overall Length	559 mm (22 in)
Overall Width	457 mm (18 in)
Overall Height	445 mm (17.5 in)
Counter Area	457 mm x 406 mm (18 x 16 in)
Chamber	279 mm Diameter x 457 mm depth (11 in Diameter x 18 in depth)
Large Trays (2)	381 mm x 152 mm x 25 mm (15 in x 9 in x 1 in)
Small Trays (2)	381 mm x 152 mm x 25 mm (15 in x 6 in x 1 in)

Weight:

Empty Reservoir	45 Kgs (95 lbs)
With Shipping Carton	48 kgs (105 lbs)
Water Reservoir Capacity	Approximately 4.54 Liters to Full Mark (1.2 gallons)

Electrical Requirements:

NOTE: A separate (dedicated) circuit is recommended for this sterilizer. The sterilizer should not be connected into an electrical circuit with other appliances or equipment unless the circuit is rated for the additional load.

100 VAC, 50/60 Hz Model	20 AMP Circuit, Single Phase
120 VAC, 60 Hz Model	15 AMP Circuit, Single Phase
220-240 VAC, 50/60 Hz Model	10 AMP Circuit, Single Phase

Maximum Power Consumption:

100 VAC, 50/60 Hz Model	1425 Watts, 14.2 A @ 100V
120 VAC, 60 Hz Model	1425 Watts, 11.9 A @ 120 V

220-240 VAC, 50/60 Hz Model ..... 1500 Watts, 6.3 A @ 240 V
Chamber Pressure at
132°C (270°F) ..... 215 kPa (31 psi)
Safety Valve Setting ..... 276 kPa (40 psi)
Certifications ..... ISO-9001 Certified

LIMITED WARRANTY

SCOPE OF WARRANTY

Midmark Corporation ("Midmark") warrants to the original purchaser its new Alternate Care products and components (except for components not warranted under "Exclusions") manufactured by Midmark to be free from defects in material and workmanship under normal use and service. Midmark's obligation under this warranty is limited to the repair or replacement, at Midmark's option, of the parts or the products the defects of which are reported to Midmark within the applicable warranty period and which, upon examination by Midmark, prove to be defective.

APPLICABLE WARRANTY PERIOD

The applicable warranty period, measured from the date of delivery to the original user, shall be one (1) year for all warranted products and components.

EXCLUSIONS

This warranty does not cover and Midmark shall not be liable for the following: (1) repairs and replacements because of misuse, abuse, negligence, alteration, accident, freight damage, or tampering; (2) products which are not installed, used, and properly cleaned as required in the Midmark "Installation" and or "Installation / Operation Manual for this applicable product. (3) products considered to be of a consumable nature; (4) accessories or parts not manufactured by Midmark; (5) charges by anyone for adjustments, repairs, replacement parts, installation, or other work performed upon or in connection with such products which is not expressly authorized in writing in advance by Midmark.

EXCLUSIVE REMEDY

Midmark's only obligation under this warranty is the repair or replacement of defective parts. Midmark shall not be liable for any direct, special, indirect, incidental, exemplary, or consequential damages or delay, including, but not limited to, damages for loss of profits or loss of use.

NO AUTHORIZATION

No person or firm is authorized to create for Midmark any other obligation or liability in connection with the products.

THIS WARRANTY IS MIDMARK'S ONLY WARRANTY AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. MIDMARK MAKES NO IMPLIED WARRANTIES OF ANY KIND INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THIS WARRANTY IS LIMITED TO THE REPAIR OR REPLACEMENT OF DEFECTIVE PARTS.

SF-1487 REV. A1

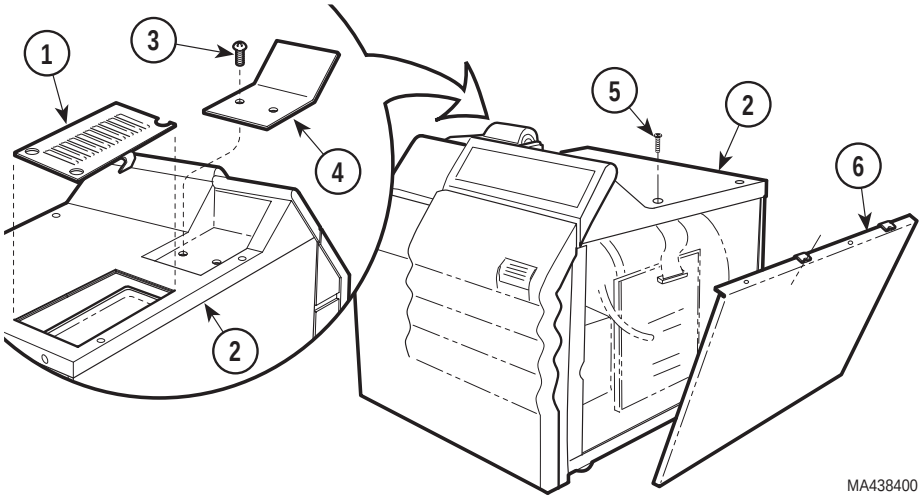
PRINTER INSTALLATION AND OPERATION

The printer is an optional add-on that some units may have. The printer may be purchased as an accessory at a later date and installed.

Installing the Printer

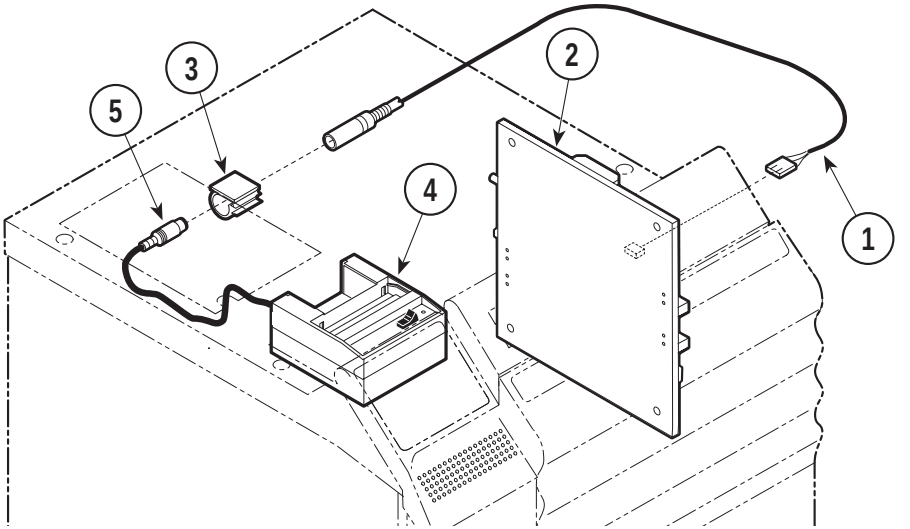
WARNING
Disconnect all electrical power to the unit before removing any of the unit's covers/ shrouds or making any repairs to prevent the possibility of electrical shock. Failure to comply with these instructions could result in serious personal injury or death.

1. Unplug the power cord from wall outlet.
2. Remove top inspection cover (1) from top cover (2).



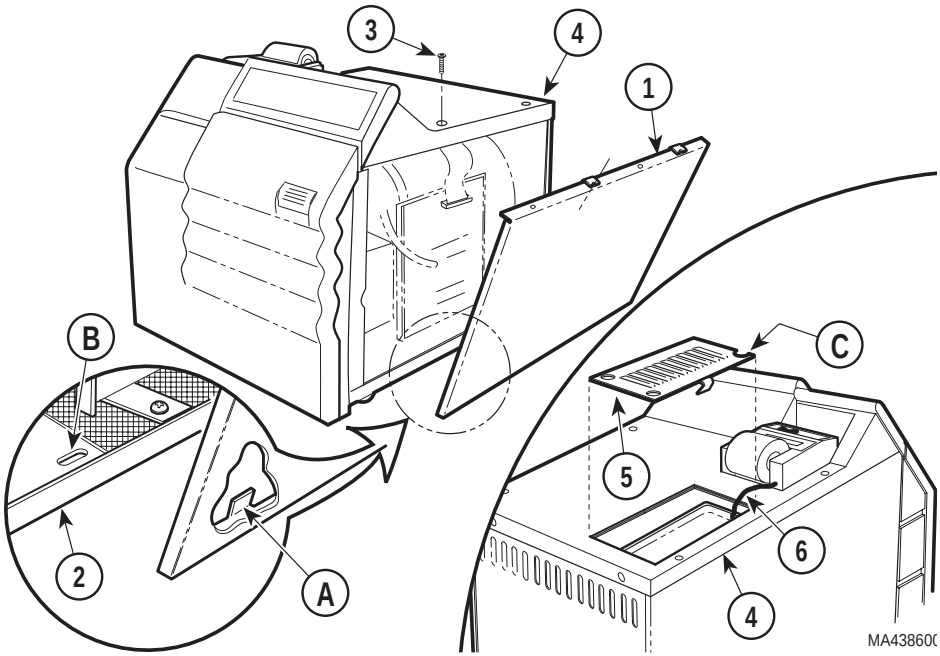
3. Remove two screws (3) and printer cover plate (4) from top cover (2). Store the two screws and printer cover plate in the event that the printer is removed and these parts are needed again.
4. Remove two screws (5) from top cover (2).
5. Pull outward and down on the top edge of the right hand side panel (6) and remove right hand side panel from sterilizer.

6. Plug PCB printer harness (1) into PC board (2).



7. Route PCB printer harness (1) through harness clip (3) to prevent harness from contacting hot pressure relief valve.
8. Place the printer (4) on the top cover in the recessed area.
9. Connect PCB printer harness (1) into printer harness (5).

10. Insert two tabs (A) of right hand side panel (1) into two slots (B) of base (2).



11. Raise top edge of right hand side panel (1) into position under top cover (4) and secure using two screws (3).

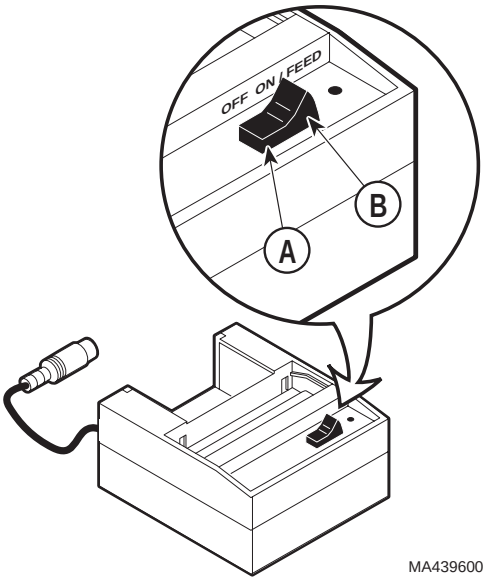
12. Install top inspection cover (5) on top cover (4), making sure PCB printer harness (6) is routed into harness cutout (C) of top inspection cover.

13. Plug power cord into wall outlet.

Operating the Printer

The paper feed switch on the printer is a rocker type switch. Push the left side (A) of the rocker switch to toggle the printer ON and OFF. Push the right side (B) of the rocker switch to ON / FEED position to advance the paper.

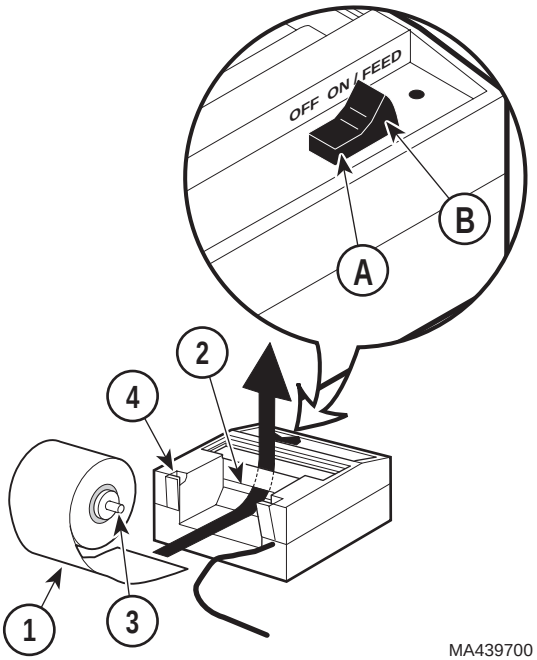
When the printer is first turned on, it prints the word READY to assure the operator that its built in microprocessor is working properly. When turning the printer OFF, wait at least 3 seconds before turning the printer back on.



MA439600

Inserting the Paper Roll

1. Press the left side (A) of the switch to toggle the printer OFF (the lamp will go out).
2. Unroll 5 to 7.5 cm (2 to 3 in.) of paper (1).
3. Cut a straight edge on the paper (1) if it is torn or jagged; this will facilitate the entry of paper into the printer.
4. Slide the paper (1) into the slot (2) on the back of the printer; it will slide in 6.4 mm (1/4 in.) before it stops.
5. Press the left side (A) of the switch to toggle the printer ON (the lamp will turn on).



MA439700

6. While holding the paper (1) in place, press the right side (B) of the switch to the ON / FEED position and hold. The printer will activate and a rubber roller will put the paper into the printer compartment. Continue to hold the switch down until the paper emerges from the top of the printer mechanism. Then, when 2.5 cm (1 in.) of paper has emerged from the top of the printer, release the switch.

7. Pull the paper (1) through the printer until 5 to 7.5 cm (2 to 3 in.) of paper is exposed.

8. Put the paper spindle (3) into the paper roll and place the roll with the spindle onto the grooves (4) at the back of the printer.

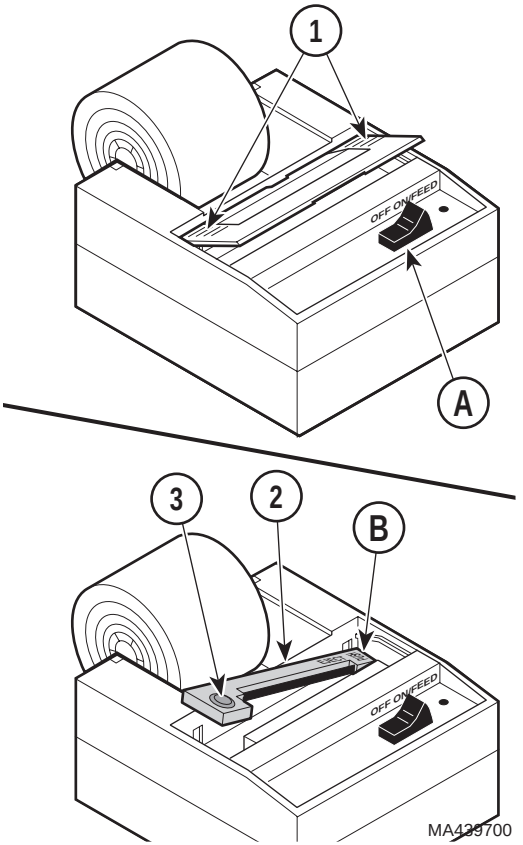
9. Turn the paper roll so as to take up the slack in the paper feeding to the printer. Make sure the roll of paper turns freely. If it does not turn freely, the paper will jam and possibly damage the printer mechanism.

About the Cartridge Ribbon

The printer takes a cartridge ribbon. When printing becomes faint or difficult to see, you should replace the cartridge. If the printer is used infrequently, the print impression sometimes becomes weak because the ribbon dries out. If the printed material is difficult to read and you suspect this is the cause of the problem, advance to a properly inked portion of the ribbon by pressing and holding the switch in the ON / FEED position for 3 seconds.

Installing a New Cartridge Ribbon

1. Press the left side (A) of the rocker switch to toggle the printer OFF (the lamp will turn off).
2. Four small grooves (1) are embossed on the left and right side of the printer cover. With the index finger of each hand, press down gently on these grooves.
3. When the printer cover (1) is tilted up to a near-vertical position, you may lift it completely off.
4. Push down on the right side (B) of the ribbon cartridge (2) (marked PUSH) and remove the old ribbon cartridge.



NOTE
If ribbon ink gets on the printer plastic case, wipe it off immediately. Once it dries, it is difficult to remove.

5. Install the new ribbon cartridge (2). Be sure the ribbon is inserted in front of the paper and the ribbon is flat against the paper. Press the ribbon cartridge (2) downward until it snaps into place.
6. Turn the knob (3) on the ribbon cartridge (marked by an arrow) clockwise to stretch the ribbon so it is tight.
7. Replace the printer cover (1).

Removing the Paper Roll

EQUIPMENT ALERT
Be sure to pull the paper out of the top of the printer (paper cutter side). Pulling the paper out of the back of the printer will damage the printer mechanism.

Before removing the paper roll, advance the paper about 2.5 cm (1 in.) beyond the paper cutter by pressing down and holding the switch to the ON / FEED position. Lift the paper roll away from the printer housing, and with a scissors, cut the paper roll feeding to the printer. Try to make the cut as straight as possible to facilitate the next reloading of the paper. Now, pull the remaining paper through the printer mechanism.

Power Up Message

When the printer is first turned on, it prints the word READY to assure the operator that its built in microprocessor is working properly. When turning the printer OFF, wait at least 3 seconds before turning the printer back on.

Printer Tape Description

The printer will print the following information for each program cycle:

Set Temperature

Set Time

Run Number

Date: a blank line is printed so that the date can be recorded on the printer tape.

The printer will print the chamber temperature, the chamber pressure, and the time elapsed in two (2) minute increments during the heat up phase.

During the actual Sterilization Phase of the program cycle, the printer will record the chamber temperature, chamber pressure, and the time elapsed for each minute of the program cycle.

When the sterilizer has completed the Sterilization Phase of the program cycle, the printer will print the word VENT to show that the steam pressure was exhausted from the chamber.

When the sterilizer has completed the Drying Phase of the program cycle, the word COMPLETE will be printed to show that the sterilizer has completed the sterilization program cycle.

The figure below shows an example of a typical printout of a program cycle:

Typical Printout of a Program Cycle

READY

BEGIN

SET TEMP:	270F	**TEMPERATURE**
SET TIME:	015	**TIME**
RUN #	001	**CYCLE NUMBER**

DATE

HEAT UP

DEG	PSI	MIN	
066	00.0	000	
066	00.0	002	
074	00.0	004	**HEAT UP**
164	00.0	006	**PHASE**
219	04.1	008	
234	09.4	010	
261	22.6	012	

STERILIZE

DEG	PSI	MIN	
272	30.2	000	
272	30.7	001	
273	31.3	002	
274	31.0	003	
273	30.7	004	
273	30.4	005	
273	30.1	006	
272	30.0	007	**STERILIZATION**
272	30.1	008	**PHASE**
272	30.4	009	
272	30.4	010	
272	30.7	011	
273	31.0	012	
273	30.8	013	
274	31.0	014	
273	30.7	015	

VENT

COMPLETE

NOTES:

NOTES:

Return To Table Of Contents

Return To Table Of Contents

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